Remarks

Claims 21-42 are pending. Claims 43-67 have been withdrawn.

Claim Rejections Under 35 U.S.C. § 102

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Chen et al. (U.S. Patent No. 6,919,370, hereinafter "Chen I") as evidenced by Fais et al (US 2008/0160106) and Casodex (Drug Information at http://www.rxlist.com/casodexdrug.htm (2009)). Applicants respectfully disagree with the rejection and request withdrawal of such rejection for the reasons stated below.

Unless a reference discloses . . . not only all of the limitations claimed but also all of the limitations ***arranged or combined in the same way as recited in the claim***, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F. 3d 1325 (Fed. Cir. 2010) (emphasis added). Moreover, the prior art reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008); *see In re LeGrice*, 301 F.2d 929, 940-44 (CCPA 1962). Thus, "[t]o anticipate, the [prior art] reference must also enable one of skill in the art to make and use the claimed invention." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001).

Chen I does not anticipate the presently claimed invention because there is no disclosure of every limitation of the claims "arranged or combined in the same way as recited in the claim". Moreover, Chen I does not enable the presently claimed invention and therefore, cannot anticipate the presently claimed invention. The Examiner points to column 7, lines 19-22 to argue that Chen I "specifically teaches" a formulation using other cancer drugs, such as cisplatin. The cited passage, however, merely presents a laundry list of compounds. It forms a minor part of a much larger summing up, which relates to drugs generally (see column 7, line 18), and which ranges from column 7, line 18 to column 7, line 64. Beyond the specific teaching on paclitaxel, which is what the invention of Chen I is directed to, nothing in Chen I enables one of ordinary skill in the art to arrive at the currently claimed invention. The specific combination of a basic drug compound, Vitamin E TPGS, a physiologically tolerable water-soluble acid, with an acid:drug compound ratio in an amount so as to be equivalent or in excess as claimed, in a solid or semi-solid formulation is not disclosed or suggested in Chen I. For example, Chen I expressly refers to formulations of "the active." From column 7, last paragraph, one would learn that the term "active" does not convey a teaching of basic drug compounds, but rather means "a

pharmaceutical", which is described "more specifically" as paclitaxel. Paclitaxel is not a basic drug compound.

Additionally, Chen I does not disclose or enable a solid or semi-solid composition. The Examiner attempts to point to a general disclosure as support that Chen I does disclose such a composition, *see, e.g.*, column 16, lines 11-18. This disclosure, however, is not sufficient to enable one of ordinary skill in the art to arrive at the currently claimed invention. Nowhere in Chen I is it disclosed that a basic drug compound in the presence of an acid can be formulated into a solid or semi-solid formulation.

Thus, in view of the above arguments, Applicants' respectfully request withdrawal of the rejection under 35 U.S.C. §102.

Claim Rejections Under 35 U.S.C. § 103

Again, Applicants note that the first rejection cited under the heading "Claim Rejections – 35 U.S.C. §103" states that the first rejection is an anticipation rejection under 35 U.S.C. 102(a,e), as being anticipated by Chen I as further evidenced by FAIS et al. (Office Action at 5). As this rejection appears in both the claim rejections relating to 102 and 103, Applicants assume that the Examiner is rejecting the claims under both sections. Applicants respectfully request that the Examiner clarify this rejection if Applicants are mistaken.

To render a claimed invention obvious under 35 U.S.C. §103, the cited reference themselves, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to combine or modify the references in such a manner necessary to arrive at the claimed invention. MPEP §2143.01. In addition, the proposed combination or modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made, *i.e.*, each of the limitations must "be found in the prior art, and not be based on applicant's disclosure." MPEP §2143.03.

The MPEP states that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP 2141. The Court in KSR quoted *In re Kahn* and stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed.

Cir. 2006). *See also KSR*, 550 U.S. at 418, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

The Court of Appeals for the Federal Circuit has described the situation where "obvious to try" is improperly equated with obviousness under §103. *See In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). In *In re O'Farrell*, the Court stated that

> [w]hat would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many choices is likely to be successful.

853 F.2d 894, 903 (Fed. Cir. 1988). The *Kubin* court held that it is improper in such circumstances to succumb to hindsight in order to select from the "combinatorial prior art possibilities" those elements needed in order to arrive at a claimed invention. *Kubin* at 1359. Rather, *Kubin* cited favorably to the United States Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) for the proposition that obviousness under §103 arises "where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions'." *Kubin* at 1359 (internal citations omitted).

Rejection of Claims 21-29, 31, 32, 34-42 under 35 U.S.C. §103(a) over Chen I in view of Fais and Casodex

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. §103 as allegedly being obvious over Chen I in view of Fais and Casodex.

The cited references, whether considered alone or in combination, do not disclose or suggest the presently claimed invention. Rather, the Examiner has pulled from the cited references only those precise elements needed to arrive at the instantly claimed invention, while failing to recognize what the cited references teach or suggest as a whole. Additionally, the Examiner has not articulated how one of ordinary skill in the art would arrive at the currently claimed invention based on the cited art. The arguments stated above regarding Chen I are equally applicable to this rejection. Chen I is directed to formulations of paclitaxel, which, as discussed above, is not a basic drug. While the specification of Chen I provides a laundry list of compounds, including cisplatin or bicualutamide, nothing in Chen I suggests that one of ordinary skill in the art could arrive at the currently claimed invention. Such a reference does not provide "strong motivation to use other cancer drugs." (Office Action at 6). Furthermore, Chen I actually teaches away from the presently claimed invention. As discussed above,

paclitaxel is not basic, and thus, the meaning of the presence of citric acid differs from what this means in the currently claimed invention. Neither Fais nor Casodex cure the deficiencies of Chen I. These references merely provide information that cisplatin and bicalutamide are weak basic drugs. Fais and Casodex do not provide any disclosure or suggestion to allow one of ordinary skill in the art to modify the formulation disclosed in Chen I to arrive at the presently claimed formulation.

Thus, for at least these reasons discussed above, the rejection is improper and should be withdrawn.

Rejection of Claims 21-42 under 35 U.S.C. §103(a) over Chen II in view of Verreck

The Examiner has also rejected Claims 21-42 under 35 U.S.C. §103(a) as allegedly being obvious over Chen et al (US 6,828,301; hereinafter "Chen II") in view of Verreck et al (WO 01/22938).

Chen II teaches that improved dispersion and dissolution performance can be achieved by adding a surfactant to a pharmaceutical composition that comprises a drug compound and an amine. (col. 15, lines 45-60, col. 15, line 61- col. 16, line 28). While Vitamin E TPGS is identified as a compound having surfactant properties, Chen II attributes the improved bioavailability of the formulation to the **amine** in the formulation. Col. 15, lines 45-60, col. 41, lines 33-35. Thus, Chen II actually teaches away from using Vitamin E TPGS, which is a physiologically tolerable water-soluble acid.

Verreck cannot cure the deficiencies of Chen II. Verreck describes basic drug compounds suitable for use as antivirals. Verreck relies on water-soluble polymers to form particles having improved bioavailability. Verrick does not describe the use of Vitamin E TPGS. Verreck also fails to describe the use of any surfactants.

Thus, nowhere in Chen II alone or in combination with Verreck is it disclosed or suggested to incorporate any surfactant, let alone the specific Vitamin E TPGS presently claimed, into the compositions disclosed in Verreck.

Thus, for at least these reasons discussed above, the rejection is improper and should be withdrawn.

Double Patenting

Claims 21-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Chen II in view of U.S. Patent No. 7,241,458. Claims 21-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Chen II in view of U.S. Patent No. 7,037,917. Claims 21-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Chen II in view of U.S. Patent No. 6,878,717. Claims 21-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Chen II in view of copending Application No. 11/930,835.

The arguments stated above with respect to Chen II address these rejections and evidence that the presently claimed invention is patentably distinct over the prior art. Thus, these arguments equally apply to the secondary references US 7,241,458, US 7,037,917, US 6,878,717 and US 11/930,835. Therefore, Applicants respectfully request withdrawal of these rejections.

CONCLUSION

Applicants maintain that the application is in condition for allowance and passage to issuance is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this reply to Deposit Account No. 10-0750/PRD2017USPCT/KKM.

Respectfully submitted,

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